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Docket No. 14598-41 (Was BEH-7443)

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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: K. Kasper et al. Examiner: M.E. Ceperley  
Serial No.: 09/368,010 Group Art Unit: 1641  
Filed: August 3, 1999 Docket: 14598-41  
Due Date: September 2, 2001 Date Mailed: August 27, 2001  
TITLE: MONOCLONAL ANTIBODIES TO TACROLIMUS AND IMMUNOASSAY METHODS FOR TACROLIMUS

**CERTIFICATE UNDER 37 CFR 1.8:** The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service, as first class mail, with sufficient postage, in an envelope addressed to: Commissioner for Patents, Washington, D.C. 20231, on August 27, 2001.

By: Joy Johnson  
Name: Joy Johnson

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

Honorable Commissioner for Patents  
Washington, DC 20231

Dear Sir:

This document is a Supplemental Information Disclosure Statement to the above-cited patent application.

Attached hereto is at least one Form PTO-1449 listing documents believed relevant to the subject application. The submission of the following information is not intended, nor should it be construed, to constitute an admission that any patent, article, or other information referred to herein is "prior art" unless specifically designated as such. In accordance with 37 C.F.R. § 1.97(b) the filing of this information shall not be construed to mean that a search has been made or that no other material information may exist. Neither should its submission be construed to indicate that a thorough search should not be conducted by the Examiner.

It is believed that this disclosure complies with the requirements of 37 C.F.R. § 1.56, § 1.97, and § 1.98 and the Manual of Patent Examining Procedures § 707.05(b). If for some reason the Examiner considers otherwise, it is respectfully requested that the undersigned be telephoned so that any deficiencies can be remedied.

This Supplemental Information Disclosure Statement is being submitted subsequent to the mailing of an International Search Report on a counterpart PCT application, which is a "communication from a foreign patent office in a counterpart foreign application" for the purposes of 37 C.F.R. § 1.97(e)(1). The International Search Report was mailed June 2, 2001. Each item of information contained in the Supplemental Information Disclosure Statement was cited in the International Search Report. However, references cited in the International Search Report that were already provided to the Patent and Trademark Office by citation in a previously-filed Information Disclosure Statement are not included here.

The undersigned further states, pursuant to 37 C.F.R. § 1.97(e)(1), that each item of information contained in the Supplemental Information Disclosure Statement was cited in the International Search Report not more than three months prior to the mailing of the Supplemental Information Disclosure Statement. Therefore, no fee is required for this Supplemental Information Disclosure Statement pursuant to 37 C.F.R. § 1.97(c)(1), and this Supplemental Information Disclosure Statement is to be considered. Should any fee be required, authorization is hereby given to charge the required fee under 37 C.F.R. § 1.197(c) and 37 C.F.R. § 1.17(p) to Deposit Account No. 16-2230.

A copy of each document is enclosed. Some of the documents may have markings thereon. No significance is meant to be attached to the markings. These documents are not necessarily analogous art. Additionally, the order of the following documents is to be accorded no particular import as the order thereof is completely fortuitous.

It is respectfully requested that these documents be: (1) fully considered by the Patent and Trademark Office during the examination of this application; and (2) represented on

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any patent which may issue on the application. Applicants respectfully request that copies of the PTO-1449 forms, as considered and initialed by the Examiner, be returned with the next communication.

U.S. Patent No. 5,635,406 to Grenier et al., issued June 3, 1997.

PCT Publication No. WO 94/25022 by Gonzalez et al., published November 10, 1994.

J.M. Murthy et al., "Tacrolimus Metabolite Cross-Reactivity in Different Tacrolimus Assays," Clin. Biochem. 31: 613-617 (1998).

A.M. Akak, "Measurement of Tacrolimus (FK506) and Its Metabolites: A Review of Assay Development and Application in Therapeutic Drug Monitoring and Pharmacokinetic Studies," Ther. Drug Monit. 19: 338-351 (1997).

Respectfully submitted,

  
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Dated: August 27, 2001

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